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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/649,879	08/28/2003	Upvan Narang	116407	7830
27049	7590	09/01/2004	EXAMINER	
OLIFF & BERRIDGE, PLC P.O. BOX 19928 ALEXANDRIA, VA 22320			PRUNNER, KATHLEEN J	
			ART UNIT	PAPER NUMBER
			3751	

DATE MAILED: 09/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/649,879

Applicant(s)

NARANG ET AL.

Examiner

Kathleen J. Prunner

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on August 28, 2003, October 17 and 27, 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-65 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-4, 6-42, 45, 49 and 53-65 is/are allowed.
- 6) ☒ Claim(s) 5, 43, 44, 46-48 and 50-52 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 August 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 101703 & 102703.
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_.

## DETAILED ACTION

### *Drawings*

1. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference signs **mentioned** in the description: **400** (note ¶s 0046 and 0048); **420** (note ¶s 0046-0049); **430** (note ¶ 0047). Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The replacement sheet(s) should be labeled "Replacement Sheet" in the page header (as per 37 CFR 1.84(c)) so as not to obstruct any portion of the drawing figures. If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

2. In addition to Replacement Sheets containing the corrected drawing figure(s), applicant is required to submit a marked-up copy of each Replacement Sheet including annotations indicating the changes made to the previous version. The marked-up copy must be clearly labeled as "Annotated Marked-up Drawings" and must be presented in the amendment or remarks section that explains the change(s) to the drawings. See 37 CFR 1.121(d). Failure to timely submit the proposed drawing and marked-up copy will result in the abandonment of the application.

### *Specification*

3. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. The following title is suggested: **APPLICATORS AND METHODS FOR APPLYING ADHESIVE MATERIAL.**

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4. The following informalities in the specification are noted: (A), in ¶s 0063 on page 15, 0069 on page 17, 0072-0075 on pages 18-19, 0077 and 0080 on page 19, 0085 on page 21, 0088 on page 22, and 0096 on page 24, the status of the applications listed should be updated. Appropriate correction is required.

5. The specification is objected to as failing to provide proper antecedent basis for the claimed terminology. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). The claimed terminology which lacks such antecedent basis is as follows: (A) "at least a central portion of the applicator tip is not secured to the reservoir and is not secured to the base strip", as called for by claim 13; (B) a medicament disposed "in or on the applicator tip", as called for by claim 16; (C) "the medicament is absorbed or adsorbed into the applicator tip", as called for by claim 17; (D) the portion of the reservoir that is ruptured "is located substantially at the axis about which the base strip is arranged to be folded", as called for by claim 20; (E) the portion of the reservoir that is ruptured "is located away from the axis about which the base strip is arranged to be folded", as called for by claim 21; (F) the portion of the reservoir that is ruptured "is arranged to be ruptured by folding the base strip about the axis", as called for by claim 22; (G) "the portion of the reservoir that is ruptured is arranged to be ruptured by pressure on the reservoir by the projection", as called for by claim 24; (H) "the projection is formed integral with the base strip", as called for by claim 25; (I) "the weakened portion is a cut in a surface of the base strip", as called for by claim 27; (J) "a method of applying an adhesive material" and its steps as called for by claims 45, 49 and 63; (K) the peel-off film "is adhered to at least one of the reservoir and the base strip at a periphery of the peel-off film", as called for by claim 54; (L) the peel-off film has a tab "outside of the periphery that is not adhered", as called for by claim 55; (M) the peel-off film "forms a bacterial barrier", as called for by claim 57; (N) "an outer packaging that surrounds the base strip, the reservoir and the applicator tip", as called for by claims 58 and 64; (O) "the outer packaging seals the base strip, the reservoir and the applicator tip", as called for by claim 59; (P) "the outer packaging forms a bacterial barrier", as called for by claim 60; (Q) "an edge outside of the

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periphery", as called for by claim 62; and (R) "peeling off the peel-off film is after rupturing the reservoir", as called for by claim 65. Correction is required. It is suggested that the specification be amended to include support for the above-mentioned claimed terminology.

6. The following informalities in the claims are noted: (A) in claim 40, on line 2, "materia" should read --material--. Appropriate correction is required.

### *Claim Rejections - 35 USC § 112*

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claim 5 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the adhesive material to be "α-cyanoacrylate" (note ¶s 0068-0070), does not reasonably provide enablement for "a cyanoacrylate formulation" as called for by claim 5. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with this claim.

9. Claims 46-48 and 50-52 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the substrate to be "living tissue" (note ¶ 0067), does not reasonably provide enablement for "tissue" as called for by claims 46-48 and 50-52. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

### *Claim Rejections - 35 USC § 102*

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:



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A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

11. Claim 43 is rejected under 35 U.S.C. 102(e) as being anticipated by Lin. Lin discloses an applicator for applying a medicinal material (note ¶ 0001) having all the claimed features including a base strip (constituted by shell 1) having a longitudinal direction (note Fig. 1), and at least one sachet (constituted by capsules 3, note Fig. 1) containing the material (note lines 48-52 in col. 3), the sachet 3 being secured to one side of the base strip 1 (note Fig. 4) wherein the base strip 1 is arranged to be folded about an axis substantially perpendicular to the longitudinal direction (note Fig. 3) such that a portion of the sachet 3 is ruptured to expel the adhesive material from the ruptured sachet 3 (note ¶ 0023). Although Lin fails to describe that the shell 1 is made of semi-rigid material, it is considered that the shell 1 is inherently made of semi-rigid material since it can maintain its shape (note Figs. 1, 2 and 4) and yet can be bent or folded back on itself (note Figs. 3 and 7). Likewise, although Lin fails to describe that pressure is applied to the folded ends to expel the material from the ruptured sachet 3, it is considered that the action of pinching the folded ends so that they can be gripped by the user (note ¶s 0008 and 0023) inherently applies pressure to the folded ends to expel the material from the applicator especially since the base strip or shell 1 is made of flexible material (note the third sentence in ¶ 0023).

### *Claim Rejections - 35 USC § 103*

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. Claim 44 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lin in view of Hitchcock, Jr. et al. Lin further discloses that the applicator is disposable (note the fourth sentence in ¶ 0024). Although Lin fails to disclose that the disposable applicator is part of a kit of a plurality of such applicators, attention is directed to Hitchcock, Jr. et al. who disclose another disposable applicator which can be formed as part of a kit of a plurality of such applicators (note Fig. 1) in order to keep the manufacturing costs low by mass producing the applicators (note lines 59-68 in col. 3). It would have been obvious to one of ordinary skill in the applicator art, at the time the invention was made, to form the applicator of Lin as a kit of a plurality of such applicators in view of the teachings of Hitchcock, Jr. et al. in order to keep the manufacturing costs low by being mass produced.

#### *Allowable Subject Matter*

14. Claims 1-42, 45, 49 and 53-65 are allowed.

#### *Conclusion*

15. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Mainwaring et al. is cited to show an applicator for cyanoacrylate adhesives that can be formed as a kit with different size applicators or different amounts of adhesive wherein the applicator can be a swab, brush or spatula and the adhesive or applicator tip can contain medicament. Redmond et al. is cited to show an applicator for applying a flowable material wherein the applicator is folded in order to rupture the reservoir to dispense the material onto an applicator pad.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Kathleen J. Prunner whose telephone number is 703-306-9044.

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17. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gregory L. Huson can be reached on 703-308-2580. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

18. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Kathleen J. Prunner

August 26, 2004



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